UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

KAREN ROBINSON & JONATHON ROBINSON, Plaintiffs, v. MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a Division of MCNEIL-PPC, INC.; and JOHNSON & JOHNSON, Defendants.	No. 07 c 5603 Judge Holderman Magistrate Judge Cox

DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF DR. PAUL WAYMACK

I. INTRODUCTION

Plaintiffs seek to exclude the testimony of Dr. Paul Waymack in its entirety on the sole basis that *some* of Dr. Waymack's opinions are purportedly at odds with the decision of the United States Supreme Court in *Wyeth v. Levine*.[1] Plaintiffs' principal complaint is that Dr. Waymack's expert report does not account for *Levine*, but his report was submitted nearly three months before that decision issued. Plaintiffs also complain that Dr. Waymack had not reviewed *Levine* by the time of his deposition, which took place less than two weeks after that decision issued.[2] Setting aside the basic unfairness of seeking to exclude expert testimony on the basis of a not-yet-decided and just-decided decision, Plaintiffs' motion misses the mark for two independent reasons. First, the vast majority of Dr. Waymack's proposed testimony has nothing to do with the *Levine* decision, and Plaintiffs' motion (which seeks wholesale exclusion of his testimony) is therefore grossly overbroad. Plaintiffs make no effort to explain why Dr.

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[1] *Wyeth v. Levine*, 129 S.Ct. 1187 (2009).

[2] That it had been less than two weeks since the Court handed down *Levine* should in and of itself suffice, were some sort of justification required, but Dr. Waymack also endured the death and burial of his mother during that time. Deposition of Paul Waymack, March 17, 2009 ("Waymack Depo."), Exhibit A to Declaration of David B. Sudzus ("Sudzus Decl."), at 226:13-22.

Waymack's unrelated opinions are otherwise inadmissible. Second, and in any event, even those portions of Dr. Waymack's report Plaintiffs assert are inconsistent with *Levine* are, in fact, consistent with that decision. For these reasons, the Court should deny Plaintiffs' motion.

II. DR. WAYMACK'S TESTIMONY

Although Plaintiffs provide the Court with only three examples of Dr. Waymack's supposedly deficient opinions taken from, at the very most, a handful of paragraphs of his 93 paragraph report, they seek to strike his testimony in its entirety.[3] Dr. Waymack's opinions, however, involve far more than the limited samples provided by Plaintiffs and Plaintiffs have not met their burden of demonstrating that *any* of Dr. Waymack's testimony should be stricken, much less that *all* of it should be disallowed. The following represents a more complete picture of the testimony that Defendants intend to elicit from Dr. Waymack, all of which (sans citations) is contained in his expert report in even more detail.[4]

A. FDA Authority Over Pharmaceutical Development.

No pharmaceutical product may be legally marketed in the United States without a conclusion by the FDA that the product is safe and effective as labeled. *See* 21 U.S.C. 355(a). To ensure a new medicine's safety and efficacy, the FDA has promulgated extensive and comprehensive regulations governing the licensing, production, testing, labeling, and final approval of each new product.[5] *See generally* 21 C.F.R. Part 201 (Labeling), Part 312 (Investigational New Drug Application), & Part 314 (Applications for FDA Approval to Market

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[3] *Compare* Pls.' Mot. at 4-5 *with id.* at 6. Plaintiffs also submit that "[t]ime and again [Dr. Waymack] expressed an understanding of FDA regulations that is directly contrary to the Supreme Court's interpretation." *Id.* at 6. Plaintiffs do not support this extremely broad statement with any citations to either Dr. Waymack's deposition or Supreme Court precedent. Defendants are not clairvoyant and are thus constrained to respond only to the information supplied by Plaintiffs in their motion.

[4] Expert Report of Paul Waymack, M.D., December 18, 2008, Exhibit B to Sudzus Decl.

[5] This Court should take judicial notice of the contents of the Federal Register. 44 U.S.C. 1507. The Code of Federal Regulations is *prima facie* evidence of the text of the original documents. 44 U.S.C. 1510(e).

a New Drug). The FDA's "new drug approval" process requires the submission of "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. 355(b)(1)(A).

This process generally begins with the submission by the sponsor or manufacturer of an Investigational New Drug Application ("IND"). 21 U.S.C. 355(i); 21 C.F.R. 312; *see* 21 C.F.R. 312.23 (IND contains information about properties or chemical composition, mechanism of action, manufacturing and purification processes, proposed protocol for clinical trial). If the FDA concludes that the clinical trial may proceed safely, the manufacturer may begin the trial under strict constraints. *See e.g.*, 21 C.F.R. 312.20—312.22 (requirements for IND), 312.53 (selecting investigators), 312.55 (informing investigators), 312.62 (recordkeeping), 312.64 (reports), 312.68 (inspections); *see also* 21 C.F.R. 56.103 (IRB review required), 56.107 (IRB membership). Throughout the duration of any clinical trial, the manufacturer updates the IND, and the FDA reassesses the provided data. 21 C.F.R. 312.32 (safety reports), 312.33 (annual reports), 312.87 (monitoring of clinical trials). The IND thus is a living document and the FDA may require changes in the protocol, or the implementation of additional safety measures, or it may stop the clinical trial altogether at any time should safety concerns arise.

When a manufacturer believes at the conclusion of the clinical trial that its data demonstrates the safety and efficacy of the medicine, it submits a New Drug Application (NDA) to the FDA so as to request marketing approval. *See* 21 C.F.R. 314.1 *et seq*. Like the IND, the NDA is a dynamic document that the manufacturer supplements as additional data becomes available. *See* 21 C.F.R. 314.50 (content of application); 314.70 (supplements), 314.80 - 81 (postmarketing reporting). The NDA includes, among other data, information concerning the medicine's safety and efficacy, as well as proposed labeling. 21 C.F.R. 314.50; *see* 21 U.S.C.

355(d) (requiring "substantial evidence . . . consisting of adequate and well-controlled investigations"). The FDA is required specifically to review and approve "the labeling proposed to be used for such drug" to assure that it contains the most authoritative and current information. 21 U.S.C. 355(b)(1)(F), 355(d); *see also* 21 C.F.R. 201.1 *et seq.* (labeling).

Even though the FDA is familiar with the drug because of the IND, it conducts a thoroughly exhaustive review of the data submitted in the NDA. *See* 21 U.S.C. 355(d); 21 C.F.R.314.50; 314.125 (noting reasons for disapproval). Among those reviewing the NDA may be physicians, scientists, chemists, pharmacologists, statisticians, and biopharmacists. 21 U.S.C. 393(b)(4) (authorizing FDA to consult with "experts in science, medicine, and public health"). Upon completion, the FDA determines whether the medicine is "safe and effective" when used in accordance with its labeling. 21 U.S.C. 355(d)(5). In other words, the FDA decides if the benefits outweigh the risks. 21 C.F.R. 314.105 (approval), 314.110 (approval letter). The manufacturer and the FDA continue this risk/benefit analysis throughout the life of the product via pharmacovigilance surveillance and constant review of the medical literature. *See, e.g.*, 21 C.F.R. 314.80 - 81.

B. FDA Authority Over The Development Of Children's Motrin.

Before Children's Motrin could be marketed by McNeil, it too was subject to compliance with the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. 301 *et seq.*, as well as the FDA regulations set forth in the Code of Federal Regulations. As set out in detail *supra*, the FDCA allows the marketing of a "new drug" *only* after the FDA has approved the drug as *safe and effective* for its intended use. 21 U.S.C. 355(a).[6] Ibuprofen, the active ingredient in Children's Motrin, had been developed in the 1960s and the FDA first approved its use in 1974. Ten years

[6] That the FDA approves a drug as safe and effective, however, does not mean that the drug has no side effects or other dangerous propensities. All drugs have side effects. Such an approval by the FDA indicates only that the benefits of the drug outweigh the risks when used pursuant to the FDA-approved labeling. 21 C.F.R. 314.105.

later, the FDA concluded that the medicine was safe enough to be marketed to adults over-the-counter—without the intervention of a healthcare provider. In 1989, McNeil obtained approval for a prescription pediatric ibuprofen product and subsequently, under the FDA's purview, began working to determine if the pediatric product was sufficiently safe for over-the-counter marketing.

During the early 1990s, the Slone Epidemiology Unit of the Boston University School of Public Health conducted the Boston University Fever Study, a prospective, randomized double blind, clinical trial with over 84,000 children enrolled. It remains to date the largest such trial of its kind in children. The study provided ample data that the medicine was safe for over-the-counter marketing.

McNeil submitted its NDA for Children's Motrin to the FDA in 1993. In other words, McNeil furnished the FDA with volumes of materials showing the technical data relating to the testing, manufacture, packaging, and sale of Children's Motrin. Among other data, McNeil presented to the FDA the results of BUFS, its pivotal clinical trial that looked at the safety and efficacy of the product. As noted, the FDA concluded that the data submitted by McNeil indicated that Children's Motrin was safe and effective for its intended over-the-counter use, thereby warranting approval. Multiple label changes have occurred since the initial approval in 1995, including a change to uniformity via class labeling, but the FDA's decision has not changed and Children's Motrin remains on the market today as a safe and effective product.

With that background information of expected testimony, we turn to Plaintiffs' argument.

III. *WYETH V. LEVINE* DEALT ONLY WITH PREEMPTION.

The *Levine* Court addressed a single question: "whether the FDA's drug labeling judgments 'preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.'" *Levine*, 129 S.Ct. at

1193. Dr. Waymack, however, will offer no opinion that the FDA's actions serve as a *complete* bar to liability.[7] His testimony applying FDA regulations to the facts of this case will help the jury understand the regulatory framework under which pharmaceutical companies labor. His opinions—as discussed below—are not in conflict with Supreme Court precedent.

A. The FDA Governs Pharmaceutical Products.

Plaintiffs first find fault with Dr. Waymack's opinion that the FDA has authority, including on drug labeling, over pharmaceutical manufacturers. Pls.' Mot. at 4. With a bit of wordsmithing, Plaintiffs attempt to have the Court view Dr. Waymack's opinions through the preemption prism. For instance, upon being cross examined with the *Levine* opinion despite his protests that he had not yet read it,[8] Dr. Waymack disagreed that a pharmaceutical manufacturer bears the "ultimate responsibility" for a drug's labeling.[9]

Plaintiffs would have the Court believe that Dr. Waymack intends to inform the jury that McNeil cannot be held responsible in a court of law for any of its labeling. When viewed in context, however, Dr. Waymack's testimony includes the unsurprising fact that the FDA must approve a manufacturer's labeling. He testified that when he was at the FDA, "when it came time to iss[ue] the initial labeling or amended labeling, in the end it was we, the FDA, who said what the final labeling was going to say."[10] He later elaborated that the FDA must "sign[] off"

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[7] Defendants do not waive any argument that, where the FDA has specifically rejected language or changes requested by a plaintiff (such as this case where the FDA specifically rejected the inclusion of such terms as SJS, TEN, and death), the claim is preempted. Defendants do not intend, though, to ascertain before the jury Dr. Waymack's opinions – rendered prior to *Levine* – concerning the FDA Preamble. As Dr. Waymack explained, the Preamble is "not statutory or administrative law. It's an explanation for what the FDA thinks and why they do things." Waymack Depo. at 209:14-19.

[8] *See* Waymack Depo. at 135:4-15 ("Since I have not had a chance to read the Supreme Court decision, as I said, I have no opinion on it."); *id.* at 136:5-137:3 ("I can't comment, having seen just this one paragraph out of the entire document . . . ."); *id.* at 137:10-22 ("Again, I have not read the entire document . . . ."); *id.* at 138:10-22 ("Again, I have not read this document, so I can't comment based on one subsection . . . .").

[9] Waymack Depo. at 137:4-9.

[10] Waymack Depo. at 58:17-24.

on any labeling.[11] And the Supreme Court agrees. *See Levine*, 129 S.Ct. at 1196 ("The FDA's premarket approval of a new drug application includes the approval of the *exact text* in the proposed label.") (emphasis added); *id.* at 1198 ("Of course, the FDA retains authority to reject labeling changes . . . .").

As a result, in a court of law under *Levine*, McNeil very well may "bear[] the responsibility for the content of its label." In a regulatory context—the context about which Dr. Waymack was testifying—it is the *FDA* that is responsible for approving or disapproving a label.

Similarly, Plaintiffs attack Dr. Waymack's opinion that the FDA has ultimate "authority" over pharmaceutical development and marketing with a citation to *Levine* that says "the manufacturer bears *responsibility* for the content of its label at all times."[13] But those are two different things: the FDA unquestionably has authority whether to approve a label, regardless whether the manufacturer has responsibility, in a court of law, for the content of that label. Plaintiffs' attempts to pit Dr. Waymack's testimony against *Levine* therefore miss the mark.

B. Dr. Waymack's CBE Opinions Are Sound.

Plaintiffs next contend that the Supreme Court "has specifically rejected" Dr. Waymack's opinions concerning the "changes being effected" (CBE) regulation, 21 C.F.R. 314.70. Pls.' Mot. at 5. The regulation in question provides that a manufacturer may implement a labeling change at the same time that it submits the change to the FDA when the change "add[s] or strengthen[s] a contraindication, warning, precaution, or adverse reaction." 21 C.F.R. 314.70(c)(2)(i) (2004). When Plaintiffs asked an overbroad question about this regulation in his deposition, Dr. Waymack properly disagreed with their interpretation:

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[11] Waymack Depo. at 136:5-137:3.

[13] Pls.' Mot. at 4 (emphasis added).

Q: Okay. Would you agree, sir, that the manufacturer of a product has always been able to change their label to add stronger warnings without getting prior FDA approval for such a labeling change?
. . .

A: I certainly disagree.[14]

He clarified, however, that there "are certain instances" when a manufacturer *can* utilize the regulation to change it label, "but as the FDA has stated in writing, it's very limited when this applies."[15] In other words, the allowance under the CBE procedure to change a label prior to FDA approval is "not absolute" and, in Dr. Waymack's opinion, applies only for "newly recognized safety issues."[16] Plaintiffs claim that the Supreme Court "has specifically rejected this exact interpretation." Pls.' Mot. at 5.

In actuality, the *Levine* Court did not. *See Levine*, 129 S.Ct. at 1196-97 (noting that the FDA explained that "newly acquired information" includes both new data and "new analyses of previously submitted data").[17] Most importantly, because Dr. Waymack testified that he *agreed* with the Supreme Court's interpretation, there is no conflict.

Q: Do you agree with the statement that the CBE isn't just related to newly acquired information but also new analysis [sic] of previously submitted data?
. . .

A: I guess so. I would say new analyses is new information, but, yes, I would agree with that.[18]

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[14] Waymack Depo. at 139:18-24.

[15] *Id.* at 140:4-141:4.

[16] *Id.* at 140:4-141:4; 148:3-9. Dr. Waymack supports his opinions with references to statute. For instance, the CBE enacting legislation in 1982 provided in relevant part that the supplements should be used to correct concerns about "*newly discovered risks*" and "would make available important *new* information." 47 Fed. Reg. 46622, 46623, 46635 (1982) (emphasis added). Likewise, the 2008 amendment sets out that a manufacturer can utilize the CBE regulation to enact a change only "to reflect newly acquired information." 73 Fed. Reg. 49609.

[17] The *Levine* Court also specifically noted that it "*need not decide* whether the 2008 CBE regulation is consistent with the FDCA and the previous version of the regulation . . . ." 129 S.Ct. at 1197 (emphasis added).

[18] Waymack Depo. at 150:11-17. *Compare id.* at 151:11-152:21 (noting that a new analysis that indicates a risk of higher severity than previously recognized can justify CBE) *with Levine*, 129 S.Ct. at 1197 ("The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light

Dr. Waymack's testimony concerning the CBE regulation is in line with the Supreme Court's opinion and it should be allowed.

C. Dr. Waymack *Agreed* That, Prior To 2007, The FDA Lacked Authority To Require Label Changes.

Similar to their CBE argument, Plaintiffs again stretch the envelope by claiming that the Supreme Court has "specifically rejected Dr. Waymack's contention regarding the FDA's authority to require additional warnings on drug labels." Pls.' Mot. at 5. But here's the kicker: Dr. Waymack *agreed in his deposition* that the FDA lacked authority prior to 2007 to require a label change.

> **Q**: Okay. Sir, would you agree with me that prior to 2007 the FDA lacked the authority to compel manufacturers to put stronger warnings on a pharmaceutical product that they were selling or making?
> . . .
>
> **A**: That depends upon the exact labeling of which you speak. The initial labeling, of course, has to say immediately what the FDA wants it to say or else it doesn't come on the market. Subsequent to the initial labeling until the 2007 amendment to the Food, Drug and Cosmetic Act, from a statutory law standpoint the FDA lacked that power.[19]

That he opined that the FDA could bring other pressure to bear on pharmaceutical companies to encourage them to change their labeling in no way undermines his agreement with the Supreme Court that, prior to 2007, the FDA lacked the *statutory* authority to *order* manufacturers to revise their labels.[20] Furthermore, although Plaintiffs did not inquire *how* the FDA could influence labeling decisions prior to the 2007 amendment, it will be helpful for the

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of subsequent developments . . . .") (quoting 73 Fed. Reg. 49607: "new analysis of data showing risks of a *different type* or of *greater severity*").

[19] Waymack Depo. at 125:13-24.

[20] Waymack Depo. at 125:25-126:22; 128:5-25.

jury to have an understanding of the FDA's power *in practice* in this regard.[21] Finally, any problems that may potentially arise with the testimony of Dr. Waymack can be cured by a motion to strike and/or through jury instructions. Plaintiffs' arguments do not support exclusion of Dr. Waymack's opinions in their entirety.

IV. CONCLUSION

This Court—not Dr. Waymack and not Plaintiffs or Defendants—will instruct the jury as to the law. That said, however, Dr. Waymack is certainly qualified to explain to the jury the federal regulatory framework within which pharmaceutical companies must operate. In fact, Plaintiffs do not attack his qualifications. Instead, they attempt to manufacture a conflict between Dr. Waymack's opinions and Supreme Court precedent when none exists. Plaintiffs' request to strike this witness's testimony in its entirety should be denied.

Dated: July 31, 2009

Respectfully submitted,

/s/ David B. Sudzus

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[21] *See id.* at 129:1-9 ("What I can state is that when I worked at the FDA, we did not have a problem getting manufacturers to change labeling when we deemed it important.").

CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2009, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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